



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 25 1988

Re: Sensor® Model Kelvin® 500
Unipolar Pulse Generator, and
Model K Unipolar Sensing Lead
Sensor Model Kelvin 500 Pulse
Generator. Model K Endocardial
Lead, Model 5000 Transceiver,
and Model 50 Lead Tester

Docket No. 88E-0269

SOLICITOR

Charles E. Van Horn, Esq.
Deputy Solicitor, Solicitor's Office
U.S. Patent and Trademark Office
Washington, D.C. 20231

JUL 27 1988
U.S. PATENT & TRADEMARK OFFICE

Dear Mr. Van Horn:

This is in regard to the application for patent term extension for U.S. Patent No. 4,543,954 filed by Purdue Research Foundation under the patent term extension provisions of 35 U.S.C. 156. The medical device claimed by the patent is Sensor® Model Kelvin® 500 Unipolar Pulse Generator, and Model K Unipolar Sensing Lead (together forming an exercise responsive cardiac pacemaker), Pre-Marketing Application (PMA) Number P870054.

A review of the Food and Drug Administration's official records indicates that the exercise responsive cardiac pacemaker, the product identified in the patent term extension application, was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4).

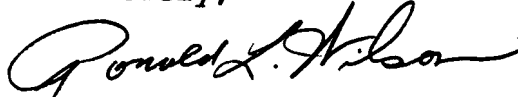
Our records also indicate that PMA number P870054 was approved on April 29, 1988, which makes the submission of the patent term restoration application received on June 27, 1988, timely within the meaning of 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. 156(d) we will then determine the applicable regulatory review period, publish that determination in the Federal Register, and notify you of our determination.

Page 2 - Mr. Charles E. Van Horn, Esq.

Please let me know if we can be of further assistance.

Sincerely,

A handwritten signature in cursive script, appearing to read "Ronald L. Wilson".

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Clifford W. Browning
Woodward, Emhardt, Naughton,
Moriarty & McNett
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